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PTO/SB/81 (10-00)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE #11

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

Docket Number (Optional) /

First named inventor: Shahin Ahmedov

Group Art Unit: 3762

Application Number: 09/988,961

Examiner: Evanisko, George Robert

Filed:

Title: Application of Digital Thermometer for Measuring Body Cardiac Output

Attention: Office of Petitions
Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703) 305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION
NOTE: A grantable petition requires the following items:

(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee--required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Adequate showing of the cause of unavoidable delay

1. Petition fee

☐ small entity - fee $ 55 (37 CFR 1.17(l)). Applicant claims small entity status. See 37 CFR 1.27.

☐ other than small entity - fee $________(37 CFR 1.17(l)).

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of hard copy & on the floppy disk (identify the type of reply):

☐ has been filed previously on ______________________.

☒ is enclosed herewith.

B. The issue fee of $ __________

☐ has been paid previously on ______________________.

☐ is enclosed herewith.

08/18/2004 EFLOKES 00000057 09988961

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PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

3. Terminal disclaimer with disclaimer fee

- [x] Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.
- [ ] A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $________ for a small entity of $_____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. An adequate showing of the cause of the delay, and that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition under 37 CFR 1.137(a) was unavoidable, is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

09.08.2004
Date

Signature

SHAHIN AHMEDOV
Typed or printed name

Telephone Number: 542 854 2207

P.O. Box 670 Near East University
Address
Lefkosha, KKTC / Mersin 10, TURKEY

Enclosures:
- [x] Fee Payment
- [x] Reply (hard copy & electronic)
- [ ] Terminal Disclaimer Form
- [ ] Additional sheets containing statements establishing unavoidable delay
- [x] Copy of postal receipt, related to previous letter

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

- [ ] deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.
- [ ] transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (703) 308-6916.

Date

Signature

Typed or printed name of person signing certificate

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

NOTE: The following showing of the cause of unavoidable delay must be signed by all applicants or by any other party who is presenting statements concerning the cause of delay.

09.08.2004
Date

Signature

Shahin Ahmedov
Typed or printed name

(In the space provided below, please explain in detail the reasons for the delay in filing a proper reply)

The letter from USPTO, mailed in December 19, 2002, requested from me to submit a substitute specification of my patent application. Due to the fact that USPTO recommended me to contact with Mr. Omar F. Khan, I sent my reply on his name in February 17, 2003 (see enclosed copy of its recepeit).
I didn't get any notification from USPTO on receiving of my letter (as in cases with all previous letters). However, 2 years of written dialogue with USPTO didn't give me any reason to think about undelivered letter.
Consequently, when I got notification of abandonment due to my unresponsiveness in July 2003, I decided that that letter was sent to me by mistake.
The following reasons made me think like this:
1. Registered letters can't be undelivered
2. The letter of abandonment from USPTO has been sent to me not by Omar F. Khan.
3. The name of examiner Mr. Evanisko has appeared on separate sheet of paper, whereas in all previous letters from USPTO personal info, related to my patent application (i.e. my name, application number, etc) always included the name of examiner as well, so that all data appeared on the same sheet of paper.

After several months of waiting I tried to check the status of my patent application and discovered that it was really abandoned due to my unresponsiveness. It was so surprisingly for me that I have decided that sooner or later but USPTO will find my letter and this "mistake" will be corrected...
In spring this year I phoned to USPTO, which confirmed that there was no any letter from me in 2003. Then, I was provided by Mr. Evanisko phone number. I failed to contact with him by phone (answering machine told that he was out of office by that time). Eventually I have found his e-mal address and got his advice on how could I try to revive my patent application (thanks to him).

Tarih damgası

Gideceği adres :—

Max Fodarello
Reception · CODE . AJ804

Teslim alan

TRUE COPY OF THE ORIGINAL

(Forma Po. 22) ENGLAND

Tarih damgası

YAKINDOĞU ÜNİV... 6-2-03 2 LEFKOŞA

61

Taahhütlü Posta Gönderisi Alınmıştır, No. ....

Tarih damgası

YAKINDOĞU ÜNİVERSİTESİ 21-2-03 2 LEFKOŞA

Kuzey Kıbrıs Türk Cumhuriyeti ... MEMURU

Gideceği adres :—

Işık
Üniversitesi

Teslim alan ....

(Forma Po. 22) İSTANBUL.

Tarih damgası

YAKINDOĞU ÜNİVERSİTESİ 7-2-03 2 LEFKOŞA

62

Taahhütlü Posta Gönderisi Alınmıştır, No. ....

Tarih damgası

YAKINDOĞU ÜNİVERSİTESİ 24-2-03 2 LEFKOŞA

Gideceği adres :—

Mr. Omar A. Khan

Teslim alan ....
USA

(Forma Po. 22)

Tarih damgası

YAKINDOĞU ÜNİVERSİTESİ 11-2-03 2 LEFKOŞA

CERTIFICATE OF NOTARY PUBLIC

I hereby certify that this is the copy of the original page, taken from the Book For Registered Letters of the Post Office at the Near East University, Nicosia.

Nicosia,
Turkish Republic of Northern Cyprus (K.K.T.C)

Subscribed and sworn to me this 09 day of 08, 2004
NOTARY PUBLIC

K.K.T.C.
LEFKOŞA NOTERİ
09 Ağustos 2004
Enver Sedat Simavi

Kuzey Kıbrıs Türk Cumhuriyeti ★ TASDİK MEMURU

100.000 TL

100.000 TL

APPLICATION OF DIGITAL THERMOMETER FOR MEASURING BODY CARDIAC OUTPUT

BACKGROUND OF THE INVENTION

1. Field of the Invention.

This invention relates to method for detemining body heart performance, ie. Cardiac Cutput, by digital thermometer.

2. State of the Prior Art.

Cardiac Output (CO) is amount of blood, pumped out by heart into blood vessels in one minute. It is calculated as $CO = SV \bullet PR$, where SV is a stroke volume, amount of blood pumpted by heart in one contraction, and PR is body pulse rate, total amount of heart contractions in one minute. In the past it was measured through catheterization of heart, ie. thermodilution technique. So-called Swan-Ganz catheter was inserted through arm or neck vein to the heart and futher up to the large vessel, which carries blood from heart to lungs. Radiological or electronical control was needed for confirmation of proper position of catheter during its insertion. Then, injection of cold solution into bloodstream on proximal side of catheter with consequent detection of a temperature change in a bloodstream on distal end of mentioned catheter was necessary for approximation of CO.

More recently, Doppler ultrasound, based on detection of reflected sound wave, was used to measure CO in outpatient setting.

The other methods and devices for measurment of CO, have been devised, all of which, however, are large, expensive, risky for the patient and require certain experience for accurate measure.

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable.

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISK

Not Applicable.

BRIEF SUMMARY OF THE INVENTION

This application describes method for measuring CO by digital thermometer.

Sensor of digital thermometer, previously cooled below skin temperature, was placed in two different locations on the forearm skin for 30 seconds each. First position was directly on the skin over arterial pulsation on the wrist, ie. on-artery position, and the second one on the skin of the back of the wrist away from the arterial pulsation, ie. off-artery position. I have found that in the former position the thermometer became warmer than in the latter position. I have also found, that an increase in thermometer's data on the skin over arterial pulsation directly correlates with person's body surface area (BSA) and pulse pressure (PP). No correlation was observed on the back of the wrist. Cardiac output is in direct correlation with BSA. Besides, cardiac stroke volume is one of the main determinants of personal PP. Thus, detection of temperature changes of cold thermometer after its contact with warm skin over arterial pulsation allows easy, safe and cost-effective calculation of cardiac output.

BRIEF DESCRIPTION OF THE DRAWINGS

The right side of FIG.1 illustrates a perspective view of digital thermometer application for blood flow assessment on the wrist and the left side – graphical presentation of average temperature increase of previously cooled digital thermometer in two positions of the wrist. The right side of FIG.2 presents a perspective view of digital thermometer application for blood flow assessment on the wrist and the left side – graphical presentation of correlations between average temperature increases of previously cooled digital thermometer in two positions on the wrist and body surface area (BSA). The right side of FIG.3 illustrates a perspective view of digital thermometer application for blood flow assessment on the wrist and the left side – graphical presentation of correlations between average temperature increases of previously cooled digital thermometer in two positions on the wrist and body pulse pressure (PP).

The right sides of all the three above-mentioned figures illustrate the approach to the evaluation of data, generated by digital thermometer after its 30 sec. contact with forearm skin. The position 1 of the sensor of digital thermometer is over arterial pulsation on the front wrist. The position 2 of the sensor of digital thermometer is on the back of the wrist, i.e. far from arterial pulsation. Close proximity of large artery to the sensor of digital thermometer at position 1 alowed to consider temperature increase of digital thermometer T_a within 30 sec. as the result of skin heat flow effect on cold thermometer by means of forced convection. The latter can be calculated by Newton's law of convection: $dQ/dt = \alpha \bullet A \bullet dT$. Distant location of the sensor of digital thermometer at position 2 from said large artery allowed to consider temperature increase of digital thermometer T_b within 30 sec. as the result of skin heat flow effect on cold thermometer by means of conduction, heat flow of which is calculated by Fourier's law of heat conduction: $dQ/dt = \lambda \bullet A \bullet dT/dx$.

All obtained results are shown graphically on the left sides of corresponding figures. Fig.1 presents average temperature increases of digital thermometer over arterial pulsation T_a and on the back of the wrist T_b ($p < 0{,}05$). Fig.2 illustrates the correlation between said average temperature changes and body surface area, BSA ($r = 0{,}65$ for T_a and $r < 0{,}5$ for T_b). Fig.3 shows the correlation between said average temperature changes and body pulse pressure, PP ($r = 0{,}58$ for T_a and $r < 0{,}5$ for T_b).

DETAILED DESCRIPTION OF THE INVENTION

Body thermometry is based on the principle of conduction, one out of four mechanisms of heat transfer, ie. radiation, evaporation, convection and conduction. Conductive way of bioheat transfer is generally used by body during its direct contact with solid objects, like in case with thermometer. Amount of heat intensity, required to warm up thermometer during its contact with skin under other equal conditions, depends on amount of blood, circulating in measured area. Thus, the rate of increase of the thermometer's data should correlate with the local blood flow and is expected to be about the same in all parts of the body. The rate of heat flow in this situation would obey to Fourier's law of heat conduction, which is

$$dQ/dt = \lambda \bullet A \bullet dT/\,dx$$

where ***dQ/dt*** is the rate of heat flow, λ is thermal conductivity, ***A*** is surface area of thermometer, ***dT*** is temperature gradient between warm skin and cold thermometer and ***dx*** is distance between blood vessel and thermometer.

However, my measurements have revealed different velocities of temperature changes at different parts of the body after the below mentioned procedures. First, sensor of digital thermometer, previously cooled down to 19°C, was placed on the skin over arterial pulsation on the front wrist for 30 sec. Lately the same procedure has been carried out for measurement on the back wrist, i.e. off-arterial pulsation. The data have been collected from 26 volunteers. These temperature data have shown that, thermometer over arterial pulsation on the front wrist each time was warmer than that of off-arterial pulsation on the back wrist. The average increase of temperature over arterial pulsation, T_a, was 4,48±0,56°C, whereas this value in off-arterial pulsation, T_b, consisted of 3,82±0,45°C ($n=26$, $p < 0,01$). The obtained difference may be explained by close position of large artery, ie. radial artery in the former case and its distant location in the latter one. The majority of observations, related to bioheat transfer intensity, consider thermal response of biotissues on environmental temperature changes as the result of changes in local capillary blood perfusion rate. On the other hand, recent theoretical analysis of this situation has indicated on the importance of large blood vessel presence for the local thermal response, occuring in biotissues (L.X.Xu. J.of Biomed.Engin.,1993,vol.115, pp.175-179). As it is presented in this report, the higher rate of heating intensity

of the skin over arterial pulsation, T_a, compared with the site, far from the arterial pulsation, T_b, can be explained by different ways of heat transfer: forced convection in the former case versus conduction in the latter. Constant blood flow velocity within artery with its constant temperature provided more rapid warming of thermometer over arterial pulsation, T_a, compared with the site far from arterial pulsation, T_b. Calculation of heat flow rate by forced convection obeys the Newton's law of convection:

$$dQ/dt = \alpha \bullet A \bullet dT$$

where dQ/dt is the rate of heat flow, α is heat transfer coefficient, A is surface area of thermometer, dT is temperature gradient between warm skin and cold thermometer.

The above-mentioned suggestion, in favour of large artery effect on warming ability of skin over arterial pulsation, has been supported by correlations, revealed between:

(i) temperature changes over arterial pulsation, i.e. T_a and body surface area *(r=0,65, n=26)* and

(ii) between T_a and pulse pressure *(r=0,58, n=26)*.

No correlation was admitted between T_b (ie. off-arterial pulsation) and above-mentioned anthropometric and hemodynamic parameters.

Personal body surface area is in direct correlation with cardiac output, amount of blood, pumped out by heart into vessels (A.C.Guyton. Human Physiol.&Mechan.of Dis., 5th Edit., 1992, p.163). So, the bigger person is, the larger vessel's diameter he would have. As a result, large arterial diameter would allow more blood flow through it with resultant high heating flow rate of skin, close to that vessel.

Pulse pressure (PP) is a difference between measured systolic and diastolic arterial pressures. E.g. in case if blood pressure is *120/80 mm Hg* then $PP = 120 - 80 = 40$ *mm Hg*. Amount of PP depends on three factors: age, arterial elastic constant and stoke volume (Ballock J, Boyle J-III, Wang MB. Physiology. 3rd Edit. Williams & Wilkins, 1994, p.130). The latter one is a constituent of cardiac output: $CO = SV \bullet PR$, where CO is cardiac output, SV is stroke volume and PR is body pulse rate So, the larger SV is, the bigger PP would be expected. Consequently, higher heat flow rate is anticipated at the arterial pulsation skin area.

The absence of such kind of correlations for T_b, can be explained by the overall capillary, rather than the arterial blood flow impact on skin bioheat transfer on the back wrist at T_b position.

ABSTRACT

The method presented in this work applies digital thermometer for non-invasive calculation of cardiac output. Higher warming velocity of digital thermometer has been detected over arterial pulsation on the wrist compared with the values, taken from the back of the wrist. Suggestions in favour of large artery blood flow effect on detected temperature changes over arterial pulsation have been approved by its correlation with body surface area and pulse pressure in 26 volunteers. The result indicates that cardiac output can be calculated through appropriate application of heat rate formulas for forced convection and conduction.

further calculate a blood flow velocity from said heat transfer parameter, and approximate the cardiac output of said patient from said blood flow velocity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwab (US Patent No 3,593,704). The claims being replete with indefinite language, the prior art of Schwab, disclosing an apparatus deriving cardiac output, pulse rate, and blood flow from skin temperature is found to anticipate the claimed invention.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Epstein (US Patent No 4,493,564). The claims being replete with indefinite language, the prior art of Epstein, disclosing an apparatus deriving cardiac output, pulse rate, and blood flow from skin temperature is found to anticipate the claimed invention.

Reply on Claim Rejections - 35 U.S.C. 102

This is a brief history of my invention, which I presented in response to examiner's Claim Rejections under 35 U.S.C. 102 (b) as being anticipated by Schwab (UsS Patent No 3,593,704) and by Epstein (US Patent No 4,493,564).

I am anesthesiologist and thermodilution is the method, generally used at intensive care units for invasive measure of cardiac output, CO (for more detailes see the State of the Prior Art). At the beginning I was trying to apply the same principle for non-invasive measure of CO. However, outside placement of cold object on skin surface on the upper arm (ie. upstream of artery) with following attempt to detect temperature decrease on lower arm (ie. downstream of the artery) did not give any result due to the reason that skin is a good insulator. Then, relying on the concept that skin heat intensity, ie. skin temperature, of a particular body area depends on amount of blood, delivered by vessels to the area in question, I tried another approach. I was going to detect
(i) how fast skin can warm up cold object within its short time contact with the skin, (ii) if this warming velocity is the same at different body parts, ie. close to arterial pulsation and far away from it, and (iii) if there are any interconnections between the obtained warming velocity of cold object and obvious body characteristics related to circulatory, ie. cardio-vascular system. The only obstacle in this case was to find the way of real-time measure of temperature of said cold object during its contact with the skin. To solve this problem a sensor of digital thermometer has been used as a cold object and a measuring device at the same time.

Below I enclose a table, expressing some key points of differences, existing between my invention and prior art.

Category	*Schwab and Epstein*	*My invention*
Arterial pulsation	Arterial pulsation was detected to count body pulse rate	Arterial blood flow effect on skin heat flow rate over arterial pulsation was estimated
Temperature	Body temperature was measured	Velocity, with which thermometer's data were changed through time during its contact with skin, was measured
Thermometer	was used at room temperature	was previously cooled down upto predetermined temperature

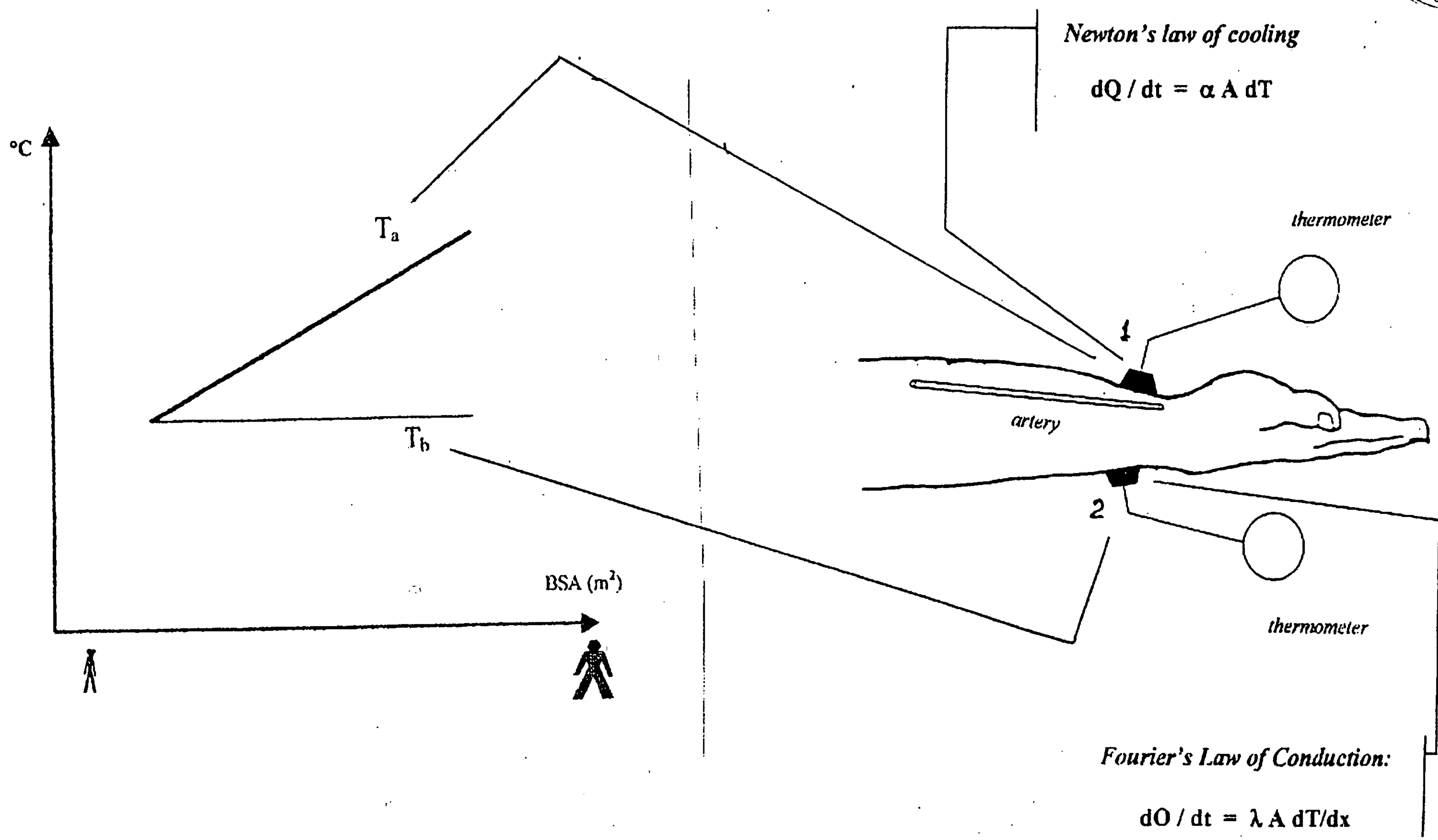
Newton's law of cooling
dQ / dt = α A dT
thermometer
1
artery
2
thermometer
Fourier's Law of Conduction:
dO / dt = λ A dT/dx
°C
Ta
Tb
BSA (m²)

FIG.2

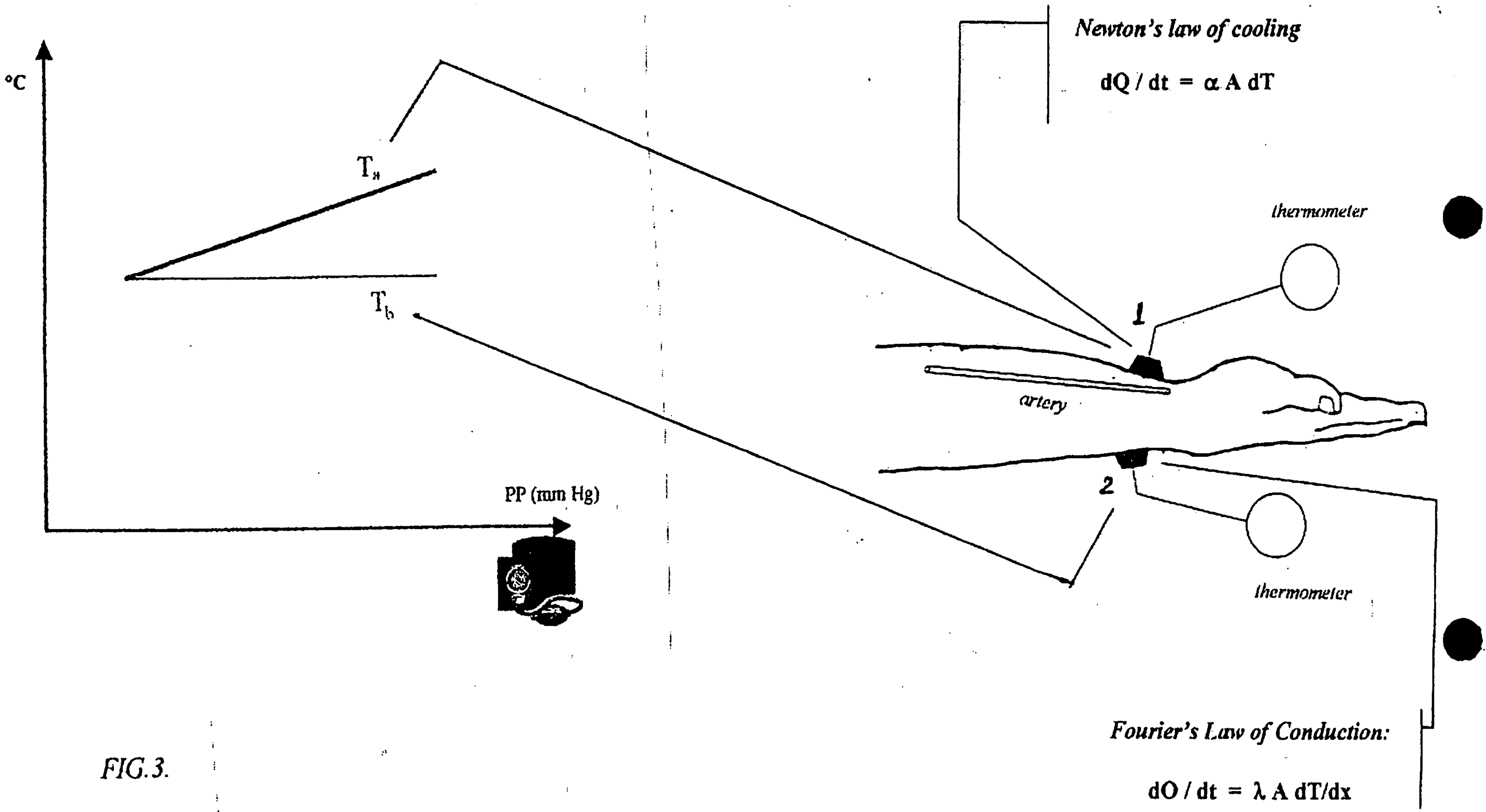
Newton's law of cooling
dQ / dt = α A dT
thermometer
1
artery
2
thermometer
Fourier's Law of Conduction:
dO / dt = λ A dT/dx
°C
Ts
Tb
PP (mm Hg)

FIG.3.

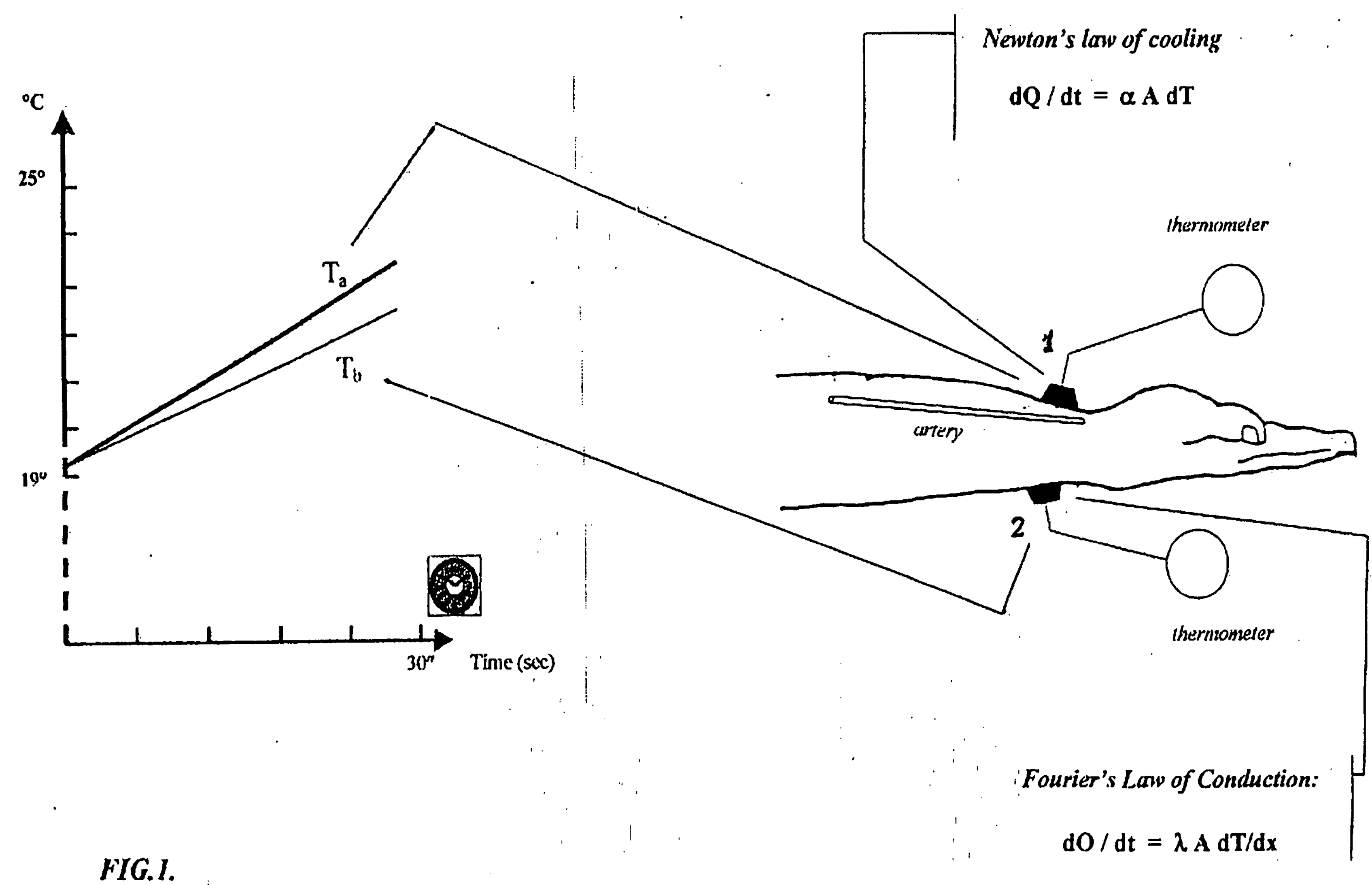
Newton's law of cooling
dQ / dt = α A dT
thermometer
1
artery
2
thermometer
Fourier's Law of Conduction:
dO / dt = λ A dT/dx
°C
25°
19°
T_a
T_b
30"
Time (sec)

FIG.1.